

Appl. No.: 10/019,563

Amendment dated June 8, 2005

Responsive to Office Action of February 8, 2005

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**5 Listing of Claims:**

Claims 1-10 (Cancelled)

11. (Currently Amended) A medical apparatus for remodeling a mitral valve annulus adjacent to the coronary sinus, comprising:

10 an elongate body having a proximal end region and a distal end region, each of the proximal and distal end regions dimensioned to reside completely within the vascular system, the elongate body being movable from a first configuration for transluminal delivery to at least a portion of the coronary sinus to a second configuration for remodeling the mitral valve annulus proximate the coronary sinus; and

15 a forming element attached to the elongate body for manipulating the elongate body from the first transluminal configuration to the second remodeling configuration;

wherein ~~the forming element is securable relative to the elongate body for retaining the elongate body in the second configuration at least in part within the coronary sinus~~ the elongate body presses a portion of the coronary sinus against the mitral valve annulus when in the second remodeling configuration.

20 12. (Currently Amended) The medical apparatus according to claim 11, wherein the forming element is secured connected to the elongate body at a point of attachment and the forming element is movable relative to the elongate body in order to adjust the elongate body within the coronary sinus between the first and second configurations.

25 13. (Currently Amended) The medical apparatus according to claim 12, wherein the forming element ~~is adapted to be severed while the elongate body is positioned at least in part~~

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~~within the coronary sinus in the second configuration~~ is maneuverable from outside the vein system for manipulating the elongate body.

14. (Canceled)

15. (Currently Amended) A medical apparatus as in claim 11, wherein the elongate  
5 body ~~defines an arc~~ assumes a reduced radius of curvature when in the remodeling configuration.

16. (Currently Amended) A medical apparatus as in claim 11, further comprising a coating on the body for avoiding thrombosis in the coronary sinus.

17. (Previously presented) A medical apparatus as in claim 11, wherein the apparatus  
10 is movable from the transluminal configuration to the remodeling configuration in response to proximal retraction of the forming element.

18. (Previously presented) A medical apparatus as in claim 11, wherein the apparatus is movable from the implantation configuration to the remodeling configuration in response to distal advancement of the forming element.

19. (Currently Amended) A medical apparatus as in claim 11, further comprising an  
15 ~~anchor~~ a first stent section disposed along the distal end region of the elongate body for retaining the apparatus at a deployment site within a vessel.

20. (Currently Amended) A medical apparatus as in claim 19, wherein the ~~anchor~~  
~~comprises a friction enhancing surface structure~~ first stent section is self-expanding for engaging the wall of the vessel.

20 21. (Currently Amended) A medical apparatus as in claim 19, wherein the ~~anchor~~  
~~comprises at least one barb for piercing the wall of the vessel~~ forming element is connected to the first stent section.

22. (Canceled)

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23. (Currently Amended) A device for effecting the condition of a mitral valve annulus of a heart comprising a resilient member having a cross sectional dimension for being received within the coronary sinus of the heart and having a longitudinal dimension ~~having an arched configuration~~ for partially encircling the mitral valve and, wherein the resilient member  
5 shortens along the longitudinal axis for exerting an inward pressure on the mitral valve when within the coronary sinus adjacent the mitral valve for constricting the mitral valve annulus.

24. (Canceled)

25. (Previously presented) The device of claim 23 wherein the resilient member has a distal end and a proximal end and wherein the resilient member longitudinal dimension is of a  
10 length to cause the proximal end of the resilient member to be proximal to the ostium of the coronary sinus.

26. (Previously presented) The device of claim 23 wherein the resilient member includes at least one fixation element.

27. (Previously presented) The device of claim 26 wherein the at least one fixation  
15 element is at a proximal end of the resilient member.

28. (Canceled)

29. (Canceled)

30. (Previously presented) The device of claim 23 wherein the resilient member is formed of an alloy including at least nickel and titanium.

20 31. (Currently Amended) A mitral valve annulus constricting device comprising a generally ~~C-shaped clip~~ U-shaped member formed of resilient material and configured to assume a reduced radius of curvature after delivery into the coronary sinus for exerting a substantially radially inward force on the mitral valve annulus ~~when placed in the coronary sinus of a heart about and adjacent to the mitral valve.~~

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32. (Currently Amended) A mitral valve therapy system comprising:  
a resilient member having a cross sectional dimension for being received within the  
coronary sinus of a heart and having a longitudinal dimension having ~~an arched~~ a bent  
configuration for partially encircling the mitral valve of the heart and exerting a substantially  
5 radially inward compressive force on the mitral valve annulus of the heart when placed within  
the coronary sinus adjacent the mitral valve, ~~the resilient member having a proximal end~~  
~~including a coupling mechanism; and~~[[,]]

an elongated ~~introducer~~ cover sheet formed of flexible material and ~~having a distal end~~  
~~including a coupling mechanism for being releasably coupled to the resilient member coupling~~  
10 ~~member for guiding the resilient member into the coronary sinus of the heart and being detached~~  
~~from the resilient member once the resilient member is placed within the coronary sinus to permit~~  
~~the introducer to be removed from the heart while leaving the resilient member positioned within~~  
~~the coronary sinus;~~

wherein the elongated cover sheet is retractable for exposing the elongate body within the  
15 coronary sinus.

33. (Canceled)

34. (Previously presented) The system of claim 32 wherein the resilient member  
longitudinal dimension is of a length to cause the proximal end of the resilient member to be  
proximal to the ostium of the coronary sinus.

20 35. (Previously presented) The system of claim 32 wherein the resilient member  
includes at least one fixation element.

36. (Previously presented) The system of claim 35 wherein the at least one fixation  
element is at the proximal end of the resilient member.

37. (Canceled)

25 38. (Canceled)

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39. (Currently Amended) The system of claim 32 wherein at least a portion of the resilient member is formed of an alloy including at least nickel and titanium a shape memory material.

40. (Currently Amended) The system of claim 32 further including an elongated  
5 ~~cylindrical sheath dimensioned for receiving the resilient member and the introducer, the sheath being flexible for advancement into the coronary sinus and guiding the resilient member into the coronary sinus~~ stabilizing instrument coupled to the resilient member for maintaining the resilient member in a desired location during retraction of the cover sheet.

41. (Canceled)

10 42. (Currently Amended) A method of treating dilated cardiomyopathy of a heart of a patient, the method including the steps of:

providing a constriction device ~~formed of resilient material having an unstressed C shape configuration with an effective radius less than a dilated mitral valve annulus radius~~ having a first state and a cross sectional dimension for being received within the  
15 coronary sinus of the heart; and

advancing the constriction device from the right atrium into the coronary sinus of the heart until the constriction device at least partially encircles the mitral ~~valve~~ valve of the heart;  
and

transferring the constriction device to a second state for pressing the coronary sinus  
20 against the mitral valve annulus.

43. (Currently Amended) The method of claim 42 wherein the advancing step includes releasably coupling the constriction device to an elongated flexible introducer and moving the constriction device from the right atrium into the coronary sinus with the introducer.

44. (Previously presented) The method of claim 43 including the further steps of  
25 releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer from the patient.

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45. (Currently Amended) The method of claim 43 including the further step of placing a cylindrical ~~sheath~~ cover sheet within the coronary sinus of the heart of the patient, the ~~sheath~~ cover sheet having a cross sectional dimension for receiving the introducer and constriction device, and wherein the advancing step includes the step of guiding the introducer and constriction device from the right atrium into the coronary sinus within the ~~sheath~~ cover sheet.

46. (Currently Amended) The method of claim 45 including the further steps of releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer and ~~sheath~~ cover sheet from the patient.

47. (Currently Amended) The method of claim 46 including the further step of retracting the ~~sheath~~ cover sheet until the ~~sheath~~ cover sheet is proximal to the constriction device prior to releasing the introducer from the constriction device.

48. (Currently Amended) A mitral valve annulus constricting device comprising a ~~generally C-shaped clip member~~ an elongate body formed of ~~resilient~~ a shape memory material and configured for insertion into a coronary sinus for exerting a ~~substantially radially~~ compressive force on the mitral valve annulus when placed adjacent to the mitral valve.

49. (Currently Amended) A method to reduce a mitral valve annulus comprising inserting an elongate body at least partially into a coronary sinus using a catheterization technique and adjusting a shape of the elongate body within the coronary sinus for pressing the coronary sinus against the mitral valve annulus.

50. (Currently Amended) A method of closing a gap in a mitral valve comprising advancing an elongate body at least partially into a coronary sinus using a catheterization technique and adjusting the elongate body from a location outside the body for pressing the coronary sinus against a mitral valve annulus of the mitral valve to close the gap.

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51. (Currently Amended) A medical device for remodeling an extravascular tissue structure adjacent to a vessel in a patient, comprising:

an elongate body extending between a proximal end and a distal end, and that is adjustable between a first configuration having a first shape such that the elongate body is adapted to be delivered at least in part into the vessel and a second configuration having a second shape such that the elongate body is adapted to exert a force from within the vessel onto the extravascular tissue structure in order to remodel the extravascular tissue structure,

wherein the elongate body is adapted to be positioned in the first configuration at least in part within a coronary sinus and is adapted to remodel a mitral valve annulus adjacent to the coronary sinus when the elongate body is located at least in part within the coronary sinus and is adjusted to the second configuration; and,

a forming element that is ~~secured~~ connected to the elongate body at a point of attachment and that is moveable in order to adjust the elongate body within the coronary sinus between the first and second configurations.

52. (Previously presented) The medical device of claim 51 wherein the forming element is moveable relative to the elongate body in order to adjust the elongate body within the coronary sinus between the first and second configurations.

53. (Previously presented) A medical device as in claim 51, wherein the elongate body is adjustable from the first configuration to the second configuration principally by applying a force from the forming element to the elongate body.

54. (Previously presented) A medical device as in claim 51, wherein the elongate body is adapted to be uncoupled in the second configuration from at least a portion of the forming element located at least in part within at least the coronary sinus.

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55. (Previously presented) A medical device as in claim 51, wherein the forming element is adapted to be severed while the elongate body is positioned at least in part within the coronary sinus in the second configuration.

56. (Previously presented) A medical device as in claim 51, wherein the proximal extension of the forming element comprises a proximal member;

the forming element further comprises a distal member that is coupled to the proximal member and is attached to the elongate body at the point of attachment;

the proximal member is adapted to transmit an applied force from outside the patient to the distal member while the elongate body along the midportion is located within the coronary sinus;

the distal member is adapted to substantially transmit the applied force from the proximal member to the elongate body in order to adjust the elongate body from the first configuration to the second configuration within the coronary sinus;

and the distal member is detachable from the proximal member while the elongate body is in the second configuration at least in part within the coronary sinus in order to thereby sever the forming element.

57. (Previously presented) A medical device as in Claim 51, wherein the forming element between the point of attachment and the proximal end portion of the elongate body is substantially circumferentially confined by the elongate body.

58. (Previously presented) A medical device as in Claim 51, wherein the forming element has a proximal extension that extends proximally from the elongate body and externally of the patient when the elongate body is located at least in part within the coronary sinus, and the elongate body within the coronary sinus is adjustable within the coronary sinus from the first configuration to the second configuration by manipulating the proximal extension outside of the patient.



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59. (Previously presented) A medical device as in claim 51, further comprising an anchor for retaining at least a portion of elongate body within the coronary sinus.

60. (Previously presented) A medical device as in claim 51, wherein the elongate body comprises a length along an axis and is adjustable from the first configuration to the second configuration principally by transmitting an axial force from the forming element onto the elongate body relative to the axis.

61. (Previously presented) A medical device as in claim 51, wherein the elongate body is adjustable from the first configuration to the second configuration in response to proximal retraction of the forming element.

62. (Previously presented) A medical device as in claim 51, wherein the elongate body is movable from the first configuration to the second configuration in response to distal advancement of the forming element.

63. (Currently Amended) A device for effecting mitral valve annulus geometry of a heart comprising:

15 a first ~~anchor~~ fixation element configured to be positioned within and fixed to the coronary sinus of the heart adjacent the mitral valve annulus within the heart;

a wire ~~fixed~~ connected to the first ~~anchor~~ fixation element and extending proximally from the first ~~anchor~~ fixation element ~~within the heart through the coronary sinus; and~~

20 a second ~~anchor~~ fixation element configured to be positioned in and fixed in the heart proximal to the first ~~anchor~~ fixation element ~~and arranged to receive the wire;~~

~~whereby when the first and second anchors are fixed within the heart, the wire is drawn proximally, and the wire is secured on the second anchor, the geometry of the mitral valve is effected~~

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wherein the wire is maneuverable from a location outside the vein system to reshape the mitral valve annulus and the first and second fixation elements are configured to hold the mitral valve annulus in a reshaped condition.

64. (Currently Amended) A method of effecting mitral valve annulus geometry in a heart, the method including the steps of:

providing an elongate body having first and second stent sections and a wire connected to the first stent section;

fixing [[a]] the first anchor stent section within the coronary sinus of the heart adjacent to the mitral valve annulus;

10 anchoring fixing [[a]] the second anchor stent section within the heart proximal to the first anchor stent section; and

fixing a wire to the first stent;

extending the wire proximally from the first anchor and through the second anchor;

displacing the wire proximally relative to the second anchor to create tension in the wire;

15 and

securing the second anchor to the wire

withdrawing the wire for pulling the first stent section toward the second stent section, thereby reshaping the coronary sinus and causing the coronary sinus to press against the mitral valve annulus.

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